AUG 1 6 2000

K001969

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Pursuant to Section 12, Safe Medical Devices Act of 1990)
7/1/99

1. Submitted by:

Medtronic, Inc.
37 A Cherry Hill Drive
Danvers MA 01923

2. Contact Name:

Fred Boucher
Regulatory Affairs Manager
(978) 777-0042

3. Trade or Proprietary Name: Medtronic® GT2 Fusion Guide Wire
Common/Classification Name: Catheter Guide Wire
Name of Predicate Device: Medtronic® GT2 Fusion Guide Wire
Classification: Class II
These wires will be available in:

.014" diameter
180cm & 300 cm length
Straight and "J" tip configurations
PTFE proximal coating
Hydrophilic distal coating

4 GT2 Fusion Guide Wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. The GT2 Fusion Guide Wires are not intended for use in the cerebral vasculature. GT2 Fusion steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

5 The major components of the device include the hypotube, core wire, spring, and forming member. The Modified GT2 Fusion Guide Wire is similar in performance to the predicate device.

6 All appropriate biocompatibility tests were successfully performed on the materials used for the Modified GT2 Fusion Guide Wires.

7 In-vitro performance testing of the modifications to the guidewire included tip tensile, hypotube joint tensile, torque strength, trackability, durability, lubricity, crimp wire joint tensile, insertion force, extraction force, and crimp wire stiffness. Test results verified that the Modified GT2 Fusion Guide Wires meet all of the applicable specifications and are deemed adequate for the intended use. The Modified GT2 Fusion Guide Wire is considered to be substantially equivalent to the following device:

- Medtronic GT2 Fusion Guide Wire (K992237)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2000

Mr. Fred Boucher
Regulatory Affairs Manager
Medtronic, Inc.
37 A Cherry Hill Drive
Danvers, MA 01923

Re: K001969
Trade Name: Medtronic® GT2 Fusion Guide Wire
Regulatory Class: II (two)
Product Code: 74 DQY
Dated: July 27, 2000
Received: July 28, 2000

Dear Mr. Boucher:

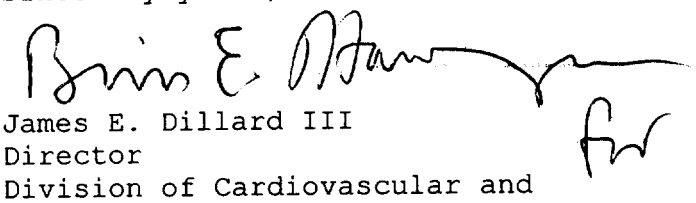
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: To be assigned by FDA

Device Name: Medtronic® GT2 Fusion Guide Wire

Indications for Use: GT2 Fusion Guide Wires are steerable guide wires that are used for the introduction and placement of diagnostic or interventional devices in the coronary and peripheral vasculature and may be used to reach and cross a target lesion. The GT2 Fusion Guide Wires are not intended for use in the cerebral vasculature. GT2 Fusion steerable exchange wires are used to facilitate the substitution of one diagnostic or interventional device for another.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Brian E. Hanson

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001969

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)